

**§ 63.360**

**40 CFR Ch. I (7–1–05 Edition)**

General provisions reference	Applies to subpart N	Comment
63.10(d)(4) .....	Yes	
63.10(d)(5) .....	No .....	§ 63.342(f)(3)(iv) and § 63.347(g)(3) of subpart N specify reporting associated with malfunctions.
63.10(e) .....	No .....	§ 63.347(g) and (h) of subpart N specify the frequency of periodic reports of monitoring data used to establish compliance. Applicable requirements of § 63.10(e) have been incorporated into § 63.347(g) and (h).
63.10(f) .....	Yes	
63.11 .....	No .....	Flares will not be used to comply with the emission limits.
63.12–63.15 .....	Yes	

[60 FR 4963, Jan. 25, 1995, as amended at 61 FR 27787, June 3, 1996]

**Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities**

SOURCE: 59 FR 62589, Dec. 6, 1994, unless otherwise noted.

**§ 63.360 Applicability.**

(a) All sterilization sources using 1 ton (see definition) in sterilization or

fumigation operations are subject to the emissions standards in § 63.362, except as specified in paragraphs (b) through (e) of this section. Owners or operators of sources using 1 ton (see definition) subject to the provisions of this subpart must comply with the requirements of subpart A, of this part according to the applicability of subpart A of this part to such sources in Table 1 of this section.

**TABLE 1 OF SECTION 63.360—GENERAL PROVISIONS APPLICABILITY TO SUBPART O**

Reference	Applies to sources using 10 tons in subpart O <sup>a</sup>	Applies to sources using 1 to 10 tons in subpart O <sup>a</sup>	Comment
63.1(a)(1) .....		Yes	Additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
63.1(a)(2) .....		Yes	
63.1(a)(3) .....		Yes	
63.1(a)(4) .....		Yes	Subpart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O.
63.1(a)(5) .....		No	Reserved.
63.1(a)(6) .....		Yes	
63.1(a)(7) .....		Yes	
63.1.1(a)(8) .....		Yes	
63.1(a)(9) .....		No	Reserved.
63.1(a)(10) .....		Yes	
63.1(a)(11) .....		Yes	§ 63.366(a) of subpart O also allows report submissions via fax and on electronic media.
63.1(a)(12)–(14) .....		Yes	
63.1(b)(1)–(2) .....		Yes	
63.1(b)(3) .....		No	§ 63.367 clarifies the applicability of recordkeeping requirements for sources that determine they are not subject to the emissions standards.
63.1(c)(1) .....		Yes	Subpart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O in this table.
63.1(c)(2) .....		Yes	Subpart O also specifies which sources are required to obtain a Title V permit in § 63.360.
63.1(c)(3) .....		No	Reserved.
63.1(c)(4) .....		Yes	
63.1(c)(5) .....		No	§ 63.360 specifies applicability.
63.1(d) .....		No	Reserved.
63.1(e) .....		Yes	

TABLE 1 OF SECTION 63.360—GENERAL PROVISIONS APPLICABILITY TO SUBPART O—Continued

Reference	Applies to sources using 10 tons in subpart O <sup>a</sup>	Applies to sources using 1 to 10 tons in subpart O <sup>a</sup>	Comment
63.2 .....		Yes	Additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence. Other units used in subpart O are defined in the text of subpart O.
63.3 .....		Yes	
63.4(a)(1)–(3) .....		Yes	Reserved.
63.4(a)(4) .....		No	
63.4(a)(5) .....		Yes	
63.4(b) .....		Yes	
63.4(c) .....		Yes	
63.5(a) .....		No	§ 63.366(b)(1) contains applicability requirements for constructed or reconstructed sources.
63.5(b)(1) .....	Yes .....	No.	
63.5(b)(2) .....		No	Reserved. See § 63.366(b)(2).
63.5(b)(3) .....		No	
63.5(b)(4) .....	Yes .....	No.	Reserved. See § 63.366(b)(3).
63.5(b)(5) .....	Yes .....	No.	
63.5(b)(6) .....	Yes .....	No.	
63.5(c) .....		No	Reserved. See § 63.366(b)(4).
63.5(d)(1)–(2) .....		No	
63.5(d)(3)–(4) .....	Yes .....	No.	See § 63.366(b)(4).
63.5(e) .....	Yes .....	No.	
63.5(f)(1)–(2) .....		No	§ 63.360 specifies applicability. § 63.360(g) specifies compliance dates for sources.
63.6(a)(1) .....		Yes	
63.6(a)(2) .....		No	Reserved. Subpart O does not contain any operation and maintenance plan requirements.
63.6(b)–(c) .....		No	
63.6(d) .....		No	§ 63.362(b) specifies when the standards apply.
63.6(e) .....		No	
63.6(f)(1) .....		No	§ 63.363 specifies parameters for determining compliance.
63.6(f)(2)(i) .....		Yes	
63.6(f)(2)(ii) .....		No	Subpart O does not contain any opacity or visible emission standards.
63.6(f)(2)(iii)–(iv) .....		Yes	
63.6(f)(2)(v) .....		No	Reserved
63.6(f)(3) .....		Yes	
63.6(g) .....		Yes	§ 63.365 also contains test methods specific to sources subject to the emissions standards.
63.6(h) .....		No	
63.6(i)(1)–(14) .....		Yes	Reserved
63.6(i)(15) .....		No	
63.6(i)(16) .....		Yes	Reserved
63.6(j) .....		Yes	
63.7(a)(1) .....		Yes	Reserved
63.7(a)(2) .....		Yes	
63.7(a)(3) .....		Yes	Reserved
63.7(b) .....		Yes	
63.7(c) .....	Yes .....	No.	Reserved
63.7(d) .....	Yes .....	No.	
63.7(e) .....		Yes	Reserved
63.7(f) .....		Yes	
63.7(g)(1) .....		Yes	Reserved
63.7(g)(2) .....		No	
63.7(g)(3) .....		Yes	Reserved
63.7(h) .....		Yes	
63.8(a)(1) .....		Yes	Reserved
63.8(a)(2) .....		Yes	
63.8(a)(3) .....		No	Reserved
63.8(a)(4) .....		Yes	
63.8(b)(1) .....		Yes	Reserved
63.8(b)(2) .....		Yes	
63.8(b)(3) .....		No	A startup, shutdown, and malfunction plan is not required for these standards.
63.8(c)(1) (i)–(ii) .....		No	

TABLE 1 OF SECTION 63.360—GENERAL PROVISIONS APPLICABILITY TO SUBPART O—Continued

Reference	Applies to sources using 10 tons in subpart O <sup>a</sup>	Applies to sources using 1 to 10 tons in subpart O <sup>a</sup>	Comment
63.8(c)(1)(iii) .....		Yes	Frequency of monitoring measurements is provided in § 63.364; opacity monitors are not required for these standards.
63.8(c)(2)–(3) .....		Yes	
63.8(c)(4)–(5) .....		No	
63.8(c)(6) .....		No	Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.
63.8(c)(7)(i)(A)–(B) .....		No	Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.
63.8(c)(7)(i)(C) .....		No	Opacity monitors are not required for these standards.
63.8(c)(7)(ii) .....		No	Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.
63.8(c)(8) .....		No	Opacity monitors are not required for these standards.
63.8(d) .....	Yes .....	No.	
63.8(e)(1) .....		Yes	
63.8(e)(2) .....		Yes	
63.8(e)(3) .....	Yes .....	No.	
63.8(e)(4) .....		Yes	
63.8(e)(5)(i) .....		Yes	
63.8(e)(5)(ii) .....		No	
63.8(f)(1)–(5) .....		Yes	
63.8(f)(6) .....		No	
63.8(g)(1) .....		Yes	§ 63.366(c)(1)(i) contains language for sources that increase usage such that the source becomes subject to the emissions standards.
63.8(g)(2) .....		No	
63.8(g)(3)–(5) .....		Yes	
63.9(a) .....		Yes	
63.9(b)(1)–(i) .....		Yes	
63.9(b)(1)(ii)–(iii) .....		No	
63.9(b)(2)–(3) .....		Yes	
63.9(b)(4)–(5) .....		No	
63.9(c) .....		Yes	
63.9(d) .....		No	
63.9(e) .....		Yes	Opacity monitors are not required for these standards.
63.9(f) .....		No	
63.9(g)(1) .....		Yes	Opacity monitors and relative accuracy testing are not required for these standards.
63.9(g)(2)–(3) .....		No	
63.9(h)(1)–(3) .....		Yes	Reserved.
63.9(h)(4) .....		No	
63.9(h)(5) .....		No	
63.9(h)(6) .....		Yes	§ 63.366(c)(2) instructs sources to submit actual data.
63.9(i) .....		Yes	
63.9(j) .....		Yes	Not applicable due to batch nature of the industry.
63.10(a) .....		Yes	
63.10(b)(1) .....		Yes	
63.10(b)(2)(i) .....		No	A startup, shutdown, and malfunction plan is not required for these standards.
63.10(b)(2)(ii) .....		Yes	
63.10(b)(2)(iii) .....		No	
63.10(b)(2)(iv)–(v) .....		No	
63.10(b)(2)(vi)–(xii) .....		Yes	

TABLE 1 OF SECTION 63.360—GENERAL PROVISIONS APPLICABILITY TO SUBPART O—Continued

Reference	Applies to sources using 10 tons in subpart O <sup>a</sup>	Applies to sources using 1 to 10 tons in subpart O <sup>a</sup>	Comment
63.10(b)(2)(xiii) .....		No	
63.10(b)(2)(xiv) .....		Yes	
63.10(b)(3) .....		No	§ 63.367 (b) and (c) contains applicability determination requirements.
63.10(c)(1) .....		Yes	
63.10(c)(2)–(4) .....		No	Reserved.
63.10(c)(5) .....		Yes	
63.10(c)(6) .....		No	
63.10(c)(7) .....		No	Not applicable due to batch nature of the industry.
63.10(c)(8) .....		Yes	
63.10(c)(9) .....		No	
63.10(c)(10)–(13) .....		Yes	
63.10(c)(14) .....	Yes .....	No.	
63.10(c)(15) .....		No	A startup, shutdown, and malfunction plan is not required for these standards.
63.10(d)(1) .....		Yes	
63.10(d)(2) .....		Yes	
63.10(d)(3) .....		No	Subpart O does not contain opacity or visible emissions standards.
63.10(d)(4) .....		Yes	
63.10(d)(5) .....		No	A startup, shutdown, and malfunction plan is not required for these standards.
63.10(e)(1) .....		Yes	
63.10(e)(2)(i) .....		Yes	
63.10(e)(2)(ii) .....		No	Opacity monitors are not required for these standards.
63.10(e)(3)(i)–(iv) .....		Yes	
63.10(e)(3)(v) .....		No	§ 63.366(a)(3) specifies contents and submittal dates for excess emissions and monitoring system performance reports.
63.10(e)(3)(vi)–(viii) .....		Yes	
63.10(e)(4) .....		No	Opacity monitors are not required for these standards.
63.10(f) .....		Yes	
63.11 .....		Yes	
63.12–63.15 .....		Yes	

<sup>a</sup> See definition.

(b) Sterilization sources using less than 1 ton (see definition) are not subject to the emissions standards in § 63.362. The recordkeeping requirements of § 63.367(c) apply.

(c) This subpart does not apply to beehive fumigators.

(d) This subpart does not apply to research or laboratory facilities as defined in section 112(c)(7) of title III of the Clean Air Act Amendment of 1990.

(e) This subpart does not apply to ethylene oxide sterilization operations at stationary sources such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals.

(f) If you are the owner or operator of a source subject to the provisions of

this subpart, you are also subject to title V permitting requirements under 40 CFR parts 70 or 71, as applicable. Your title V permitting authority may defer your source from these permitting requirements until December 9, 2004, if your source is not a major source and is not located at a major source as defined under 40 CFR 63.2, 70.2, or 71.2, and is not otherwise required to obtain a title V permit. If you receive a deferral under this section, you must submit a title V permit application by December 9, 2005. You must continue to comply with the provisions of this subpart applicable to area sources, even if you receive a deferral from title V permitting requirements.

(g) The owner or operator shall comply with the provisions of this subpart as follows:

(1) All sterilization chamber vents subject to the emissions standards in § 63.362 with an initial startup date before December 6, 1998, no later than December 6, 1998.

(2) All sterilization chamber vents subject to the emissions standards in § 63.362 with an initial startup date on or after December 6, 1998, immediately upon initial startup of the source.

(3) All sterilization chamber vents at sources using less than 1 ton of ethylene oxide that increase their ethylene oxide usage after December 6, 1998 such that the sterilization chamber vent becomes subject to the emissions standards in § 63.362(c), immediately upon becoming subject to the emission standards.

(4) All aeration room vents subject to the emissions standards in § 63.362 with an initial startup date before December 6, 2000, no later than December 6, 2000.

(5) All aeration room vents subject to the emissions standards in § 63.362 with an initial startup date on or after December 6, 2000, immediately upon initial startup of the source.

(6) All aeration room vents at sources using less than 10 tons that increase their ethylene oxide usage after December 6, 2000, such that the aeration room vents become subject to the emissions standards in § 63.362, immediately upon becoming subject to the emission standards.

(7)-(10) [Reserved]

[59 FR 62589, Dec. 6, 1994, as amended at 61 FR 27788, June 3, 1996; 63 FR 66994, Dec. 4, 1998; 64 FR 67793, Dec. 3, 1999; 64 FR 69643, Dec. 14, 1999; 66 FR 55582, Nov. 2, 2001]

#### § 63.361 Definitions.

Terms and nomenclature used in this subpart are defined in the Clean Air Act (the Act) as amended in 1990, §§ 63.2 and 63.3 of subpart A of this part, or in this section. For the purposes of subpart O, if the same term is defined in subpart A and in this section, it shall have the meaning given in this section.

*Aeration room* means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

*Aeration room vent* means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

*Baseline temperature* means a minimum temperature at the outlet from the catalyst bed of a catalytic oxidation control device or at the exhaust point from the combustion chamber of a thermal oxidation control device.

*Chamber exhaust vent* means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

*Compliance date* means the date by which a source subject to the emissions standards in § 63.362 is required to be in compliance with the standard.

*Deviation* means any instance in which an affected source, subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standard;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limitation (including any operating limit) or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.

*Effective date* means the date of promulgation in the FEDERAL REGISTER notice.

*Initial startup date* means the date when a source subject to the emissions standards in § 63.362 first begins operation of a sterilization process.

*Manifolding emissions* means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

*Maximum ethylene glycol concentration* means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when